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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,460	02/10/2004	H. Kim Bottomly	2002834-0235	1364
24280	7590	08/10/2004	EXAMINER	
Choate, Hall & Stewart Exchange Place 53 State Street Boston, MA 02109			HUYNH, PHUONG N	
		ART UNIT		PAPER NUMBER
				1644

DATE MAILED: 08/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/775,460	BOTTOMLY ET AL.	
Examiner	Art Unit		
Phuong Huynh	1644		

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE One MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 2/10/04.

2a)  This action is **FINAL**.                            2b)  This action is non-final.

3)  'Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## **Disposition of Claims**

4)  Claim(s) 282-337 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5)  Claim(s) \_\_\_\_\_ is/are allowed.  
6)  Claim(s) \_\_\_\_\_ is/are rejected.  
7)  Claim(s) \_\_\_\_\_ is/are objected to.  
8)  Claim(s) 272-337 are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All    b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
    Paper No(s)/Mail Date \_\_\_\_\_.  
4)  Interview Summary (PTO-413)  
    Paper No(s)/Mail Date. \_\_\_\_\_.  
5)  Notice of Informal Patent Application (PTO-152)  
6)  Other: \_\_\_\_\_.  
\_\_\_\_\_

Art Unit: 1644

### **DETAILED ACTION**

- I. The location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1644, Group 1640, Technology Center 1600.
- II. Claims 282-337 are pending.

#### ***Election/Restrictions***

- III. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  1. Claims 282-302, drawn to a method of modulating an immune system response to an allergen comprising the steps of isolating from an individual one or more professional antigen presenting cells, exposing said cells to a specific allergen and a specific factor and administering the allergen-exposed **pAPC** to the individual, classified in Class 435, subclass 7.21; Class 424, subclass 93.7, 275.1.
  2. Claims 303-337, drawn to a method of modulating an immune system response to an allergen comprising the steps of isolating from an individual one or more professional antigen presenting cells, exposing said cells to a specific allergen and a specific factor, contacting the antigen-exposed **pAPC** with **T cells** and administering the **T cells** to the individual, classified in Class 435, subclass 7.21; Class 424, subclass 93.71, 275.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups 1-2 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the claimed methods differs with respect to the method steps and endpoints. Therefore, they are patentably distinct.

- IV. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject

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matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods comprising the distinct method steps. Further, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

V. Irrespective of whichever group the applicant may elect, the applicant is further required under 35 U.S.C. 121 to elect:

If Group 1 or 2 is elected, the Applicant is required to elect a specific combination comprising a **specific allergen** such as modified or unmodified crude allergen, a **specific factor** such as the ones recited in claims 282, 303, 305, 323, and 328, a **specific antigen presenting cell** such as the ones recited in claim 286, 307 and 326, a **specific microbial extract** such as the ones recited in claim 291, 306, 325 and 329, a **specific targeting agent** such as the ones recited in claim 293, 314, and 331 for the claimed method. These modified and unmodified allergen respect to their structures and physiochemical properties. These stimulating factor differ with respect to their structures and physiochemical properties. These microbial extract differ with respect to their structures and physiochemical properties. These targeting agents differ with respect to their target specificity. Therefore, they are patentably distinct.

VI. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 282, 303, and 323 are generic.

VII. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

VIII. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

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IX. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

X. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

XI. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

XII. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The IFW official Fax number is (703) 872-9306.

XIII. Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phuong N. Huynh, Ph.D.

Patent Examiner

August 9, 2004

*Christina Chan*  
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SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600